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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,172	08/07/2003	Wayne A. Border	66821-236	3802
41552	7590	11/30/2006	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			GAMBEL, PHILLIP	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/638,172	BORDER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Phillip Gabel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 September 2006.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.  
 4a) Of the above claim(s) 3,4,8,9,11,12 and 16-18 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2,5-7,10,13-15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 9/22/06 has been entered.

Claims 1-18 are pending.

Claims 1-2, 5-7, 10, and 13-15 as they read on methods of treating glomerulonephritis with anti-TGF- $\beta$  antibodies are under consideration in the instant application.

Claims 3-4, 8-9, 11-12 and 16-18 have been withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected inventions.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

This Action will be in response to applicant's amendment, filed 9/22/06.

The rejections of record can be found in previous Office Actions, mailed 12/3/04 and 8/25/05.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Again, applicant should amend the first line of the specification to update the status of the priority documents.

4. Claims 1, 5-7, 10, 13 and 15 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Dasch et al. (U.S. Patent No. 5,772,998) (see entire document) for the reasons of record.

Applicant's arguments, filed 9/22/06, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same of record, which are reiterated herein for applicant's convenience.

As indicated previously, upon reconsideration of applicant's previous arguments in conjunction with the disclosure of the appropriate priority documents of the prior art, the previous rejection under provision of 35 U.S.C. § 102(e) has been withdrawn as it applies to methods of treating glomerulonephritis with anti-TGF- $\beta$  antibodies appears to be free of the prior art.

However as indicated previously, the claims are not limited to said "methods of treating glomerulonephritis with anti-TGF- $\beta$  antibodies".

Accordingly, the rejection of the claimed methods not limited to said "methods of treating glomerulonephritis with anti-TGF- $\beta$  antibodies" are maintained for the reasons of record.

Dasch et al. teach the use of TGF- $\beta$ -specific antibodies to neutralize the effects of TGF- $\beta$ , including lung fibrosis, liver cirrhosis fibrotic skin disorders and scarring (see entire document, including columns 5-6 and the Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat various fibrotic conditions with the same neutralizing TGF- $\beta$ -specific antibodies encompassed by the claimed methods.

Although applicant continues to argue that the examiner has not met the burden of determining the inherent characteristics of the prior art teachings, applicant has not provided any objective evidence to support their position.

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Although the reference is silent about "decreasing the production of a proteoglycan by a cell wherein the proteoglycan is selected from the group consisting of biglycan and decorin, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

"{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See MPEP 2145.

It seems reasonable on this record that the teachings of Dasch et al. on the use of TGF- $\beta$ -specific antibodies to neutralize the effects of TGF- $\beta$ , including lung fibrosis, liver cirrhosis fibrotic skin disorders and scarring would necessarily meet applicant's claimed methods, given the administration of the same agent (TGF- $\beta$ -specific antibodies) in the same or nearly the same patients with the same or nearly the same fibrotic conditions associated with extracellular matrix formation.

Applicant's arguments have not been found persuasive.

5. Claims 1-2, 5-7, 10, and 13-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 and 35 of copending application USSN. 08/349,479.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims of both the instant and copending applications are drawn to the same or nearly the same methods of treating glomerulonephritis with anti-TGF- $\beta$  antibodies as they read on the elected invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Again, applicant defers responding to the provisional rejection at this time.

6. Claims limited to methods of treating glomerulonephritis with anti-TGF- $\beta$  antibodies appear to be free of the prior art.

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7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office Action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).  
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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November 21, 2006